

Remarks

Claims 7, 10, and 12-35 are pending in the application. Claims 12-35 stand withdrawn from consideration pursuant to a restriction requirement.

Claims 7 and 10 have been amended to reflect that the peptides recited in these claims consist of the indicated sequence of amino acids.

Response to Section 112, 1st Paragraph Rejection

Claims 7 and 10 have been rejected for allegedly failing to comply with the written description and enablement requirements of Section 112. Without acquiescing in the rejection, the claims have been amended to recite a composition comprising a peptide, wherein the peptide consists of the recited sequence of amino acids. The amendment to claims 7 and 10 is believed sufficient to overcome the ground of rejection.

Response to Section 102 Rejection

Claim 7 and 10 have been rejected as allegedly anticipated by Saitoh *et al.*, WO 94/09808 ("Saitoh").

The Examiner alleges that claim 7 is drawn to a composition comprising amino acids SMRER, which is alleged to be anticipated by Saitoh SEQ ID NO:17.

Claim 7 and 10 have been amended to more particularly point out and define the invention as a composition comprising a peptide, wherein the peptide consists of the sequence of amino acids SMRER (SEQ ID NO:4) (for claim 7) or the sequence of amino acids RER (SEQ ID NO: 9) (for claim 10). The Saitoh SEQ ID NO:17 peptide, which has the sequence MVQSMRERHKAELREKA, does not anticipate claim 7. The Saitoh peptide does not consist of the sequence of amino acids SMRER, but only subsumes the amino acids SMRER as part of a larger peptide. There is no reference anywhere in Saitoh to the peptide SMRER. Saitoh does not teach the peptide SMRER, and can not therefore anticipate claim 7.

Claim 10 is not anticipated by Saitoh. Examiner's attention is again directed to the "(-)" entry for RER in the table at page 18 (Peptide M3), and the further disclosure at lines 24 to 26 indicating that RER was devoid of the desired growth promoting activity. On the basis of the

perceived inactivity of RER (and also RERMS), and other experimental results, Saitoh concluded that at least five amino acids including RERMS (or five amino acids with like side-chain properties) were essential for biological activity. Saitoh's invention is thus claimed and disclosed in such terms (page 75 *et seq.*, and page 4, line 34 to page 11, line 31).

Thus, the passages to which Examiner refers extending from page 9 to page 11 are concerned entirely with perceived biological activity of peptides including a sequences of five or more amino acids. RER is not such a peptide. Biological activity of RER is therefore not taught by Saitoh. Saitoh therefore gives no incentive to provide the pharmaceutical composition of amended claim 1. Claim 10 is not anticipated by Saitoh.

Claim 10 is moreover not obvious over Saitoh, as Saitoh teaches a lack of biological activity in RER and away for the composition of claim 10. The composition of claim 10 is inventive in view of the present inventors' discovery that RER does indeed have a biological activity, as disclosed in the present application.

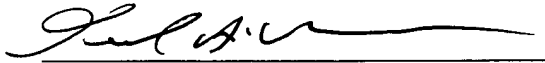
Conclusion:

Claims 7 and 10, directed to pharmaceutical compositions, are believed to be in condition for allowance. An early action toward that end is earnestly solicited. Claims 14, 18, 22, 26, 30, 34, depend from either claim 7 or 10, and recite treatment methods using the claim 7 or 8 compositions. Pursuant to MPEP 809.04, claims 14, 18, 22, 26, 30 and 34 should be rejoined with claims 7 and 10, upon allowance of the latter.

Respectfully submitted

RADMILA MILEUSNIC, *et al.*

BY



DANIEL A. MONACO

Reg. No. 30,480

DRINKER, BIDDLE & REATH, LLP.

One Logan Square

18th and Cherry Streets

(215) 988-3312

(215) 988-2757 – fax

Attorney for the Applicants